

ORAL ARGUMENT NOT YET SCHEDULEDNo. 24-5235

IN THE

United States Court of Appeals
for the District of Columbia Circuit

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellant,

v.

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*,
Defendants-Appellees,
and

MSN PHARMACEUTICALS INC., *et al.*,
Intervenor-Appellees.

On Appeal from the United States District Court
for the District of Columbia, No. 24-cv-02234
Before the Honorable Dabney L. Friedrich

MOTION TO CONSOLIDATE APPEALS

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October 15, 2024

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CERTIFICATE OF PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28.1(a)(1), Novartis Pharmaceuticals Corporation certifies that:

A. PARTIES

1. The following are parties in this Court:
 - a. Plaintiff-Appellant: Novartis Pharmaceuticals Corporation.
 - b. Defendant-Appellees: Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services, and Robert M. Califf, in his official capacity as the Commissioner of the Food and Drug Administration.
 - c. Intervenor-Defendants: MSN Pharmaceuticals Inc. and MSN Laboratories Private Ltd.
2. For purposes of Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1, Novartis Pharmaceuticals Corporation certifies that Novartis Finance Corporation is its direct parent corporation, and that Novartis Pharmaceuticals Corporation is an indirect, wholly-owned subsidiary of Novartis AG.

B. RULINGS UNDER REVIEW

Plaintiff-Appellant appeals an order and memorandum opinion issued on October 13, 2024, by District Judge Dabney L. Friedrich, ECF Nos. 65 & 64. This order and opinion denied Plaintiff-Appellant's Motion for Summary Judgment (ECF No. 38) and granted Defendants-Appellees' Cross-Motions for Summary Judgment (ECF Nos. 43, 46).

C. RELATED CASES

The appeal docketed as *Novartis Pharmaceuticals Corp. v. Becerra* (D.C. Cir. No. 24-05186) is a related case under Circuit Rule 28(a)(1)(C).

/s/ Catherine E. Stetson
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GLOSSARY

ANDA	Abbreviated New Drug Application
APA	Administrative Procedure Act
FDA	Food and Drug Administration
MSN	MSN Pharmaceuticals

INTRODUCTION

This appeal challenges the Food and Drug Administration's (FDA) approval of a purported generic drug referencing Novartis's product, ENTRESTO® (sacubitril/valsartan), after FDA unlawfully concluded the product is the "same" as Novartis's brand-name product. That is the same subject of the appeal pending before this Court in *Novartis Pharms. Corp v. Becerra*, No. 24-5186 (D.C. Cir.), which arises out of the same litigation. The cases should be consolidated, and the stay pending appeal this Court granted in the earlier-filed case should remain in place pending the merits resolution of the consolidated appeal.

BACKGROUND

The relevant factual background is set out in Novartis's motion for a stay pending appeal, filed on August 15, 2024 in the related action. *Novartis Pharms. Corp. v. Becerra*, No. 24-5186 (D.C. Cir.).

The District Court first denied Novartis's motion for a preliminary injunction. This Court reached a different conclusion, finding that Novartis "satisfied the stringent requirements for a stay pending appeal" in its August 19, 2024 Order staying FDA's action. Order, *Novartis Pharms. Corp v. Becerra*, No. 24-5186 (D.C. Cir.) (citing *Nken v. Holder*, 556 U.S. 418, 434 (2009) and D.C. Circuit Handbook of Practice and Internal Procedures 33 (2021)). In that Order staying FDA's action, the Court necessarily found that Novartis had "made a strong showing that [it] is

likely to succeed on the merits” of its Administrative Procedure Act (APA) challenge. *Nken*, 556 U.S. at 434.

Summary judgment briefing in the District Court focused on the same legal question raised at the preliminary-injunction stage: whether FDA complied with its statutory and regulatory mandate to approve only a generic drug that is the “same” as its reference listed product. In addition to its arguments that FDA approved a product that does not have the same labeling as ENTRESTO, Novartis argued that the administrative record showed that FDA unlawfully approved the purported generic even though it does not share the same active ingredients as ENTRESTO. On October 13, however, the District Court denied Novartis’s motion for summary judgment and granted FDA’s and intervenor MSN Pharmaceuticals’ (MSN) cross-motions for summary judgment.

ARGUMENT

Consolidation is appropriate here because the appeals arise from the same underlying District Court proceeding and because Novartis is challenging the same FDA action in both cases.

The Court may consolidate closely related appeals that arise from the same district court proceeding. D.C. Circuit, Handbook of Practice and Internal Procedures 24 (2021) (“[T]he Court generally will consolidate, on its own motion or on motion of the parties, all appeals and cross-appeals from the same district court

judgment or order.”); *see also, e.g., United States v. Reese*, 993 F.2d 254, 256 (D.C. Cir. 1993) (describing policy as “the practice of this circuit”); *Ibrahim v. District of Columbia*, No. 96-7069, 1997 WL 215796, at *1 (D.C. Cir. Apr. 22, 1997) (appeals that “arise out of the same district court case” are consolidated). The appeals here meet that criteria.

There is a second basis for consolidation here as well, given that the appeals involve the same parties and closely related questions of law and fact. D.C. Circuit, Handbook of Practice and Internal Procedures 24 (2021) (“In addition, other cases involving essentially the same parties or the same, similar, or related issues, may be consolidated.”). Both appeals raise the lawfulness of FDA’s action in approving an Abbreviated New Drug Application (ANDA) referencing Novartis’s product. And both appeals share the same combination of parties: Novartis, FDA, and intervenor MSN. A consolidated briefing schedule will serve the interests of the parties and judicial economy, as will assigning both appeals to the same merits panel.

CONCLUSION

For these reasons, the Court should consolidate the appeals and order that the stay issued in the earlier-filed lead appeal remain in place pending the merits resolution of the consolidated appeal.

Respectfully submitted,

/s/ Catherine E. Stetson

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Dated: October 15, 2024

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g)(1), the undersigned hereby certifies that this document complies with the type-volume limitation of Fed. R. App. P. 27(d)(2).

1. Exclusive of the exempted portions of the document, as provided in Fed. R. App. P. 32(f), this document contains 627 words.

2. The document has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14-point Times New Roman font. As permitted by Fed. R. App. P. 32(g)(1), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

October 15, 2024

/s/ Catherine E. Stetson
Catherine E. Stetson

CERTIFICATE OF SERVICE

I certify that on October 15, 2024, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

/s/ Catherine E. Stetson
Catherine E. Stetson